Package leaflet: Information for the patient

Ibuprofen B. Braun 600 mg solution for infusion
ibuprofen

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Ibuprofen B. Braun is and what it is used for
2. What you need to know before you are given Ibuprofen B. Braun
3. How Ibuprofen B. Braun is given
4. Possible side effects
5. How to store Ibuprofen B. Braun
6. Contents of the pack and other information

1. What Ibuprofen B. Braun is and what it is used for

Ibuprofen belongs to the group of medicines called "nonsteroidal anti-inflammatory drugs" or (NSAIDs).

This medicine is used in adults for the short-term symptomatic treatment of acute moderate pain when administration by intravenous route is clinically justified, when other routes of administration are not possible.

2. What you need to know before you are given Ibuprofen B. Braun

Ibuprofen B. Braun must not be given:

- If you are allergic to ibuprofen or any of the other ingredients of this medicine (listed in section 6).
- If you have ever suffered from shortness of breath, have had asthma, skin rash, itchy runny nose or facial swelling, when previously taking ibuprofen, acetylsalicylic acid or other similiar painkiller (NSAIDs).
- If you have a condition which increases your tendency or active bleeding.
- If you have active, or history of recurrent (two or more episodes) stomach ulcer or bleeding.
- If you have ever had bleeding or a tear in your stomach or gut when taking NSAIDs.
- If you are suffering from bleeding in the brain (cerebrovascular bleeding) or other active bleeding.
- If you suffer from severe kidney, liver or heart problems.
- If you are suffering from severe dehydration (caused by vomiting, diarrhoea or insufficient fluid intake).
- If you are in the last trimester of pregnancy.

Warnings and precautions

Talk to your doctor or nurse before using this medicine.

Anti-inflammatory/pain-killer medicines like ibuprofen may be associated with a small increased risk of heart attack or stroke, particularly when used at high doses. The recommended dose or duration of treatment should not be exceeded.

Skin reactions
Serious skin reactions have been reported in association with ibuprofen treatment. You should stop using Ibuprofen B. Braun and seek medical attention immediately, if you develop any skin rash, lesions of the mucous membranes, blisters or other signs of allergy since this can be the first signs of a very serious skin reaction. See section 4.

Discuss your treatment with your doctor before receiving Ibuprofen B. Braun:

- If you have heart problems including heart failure, angina (chest pain), or if you have had a heart attack, bypass surgery, peripheral artery disease (poor circulation in the legs or feet due to narrow or blocked arteries), or any kind of stroke (including 'mini-stroke' or transient ischaemic attack "TIA").
- If you have high blood pressure, diabetes, high cholesterol, have a family history of heart disease or stroke, or if you are a smoker.
- If you have just had major surgery.
- If you have had or developed an ulcer, bleeding or perforation of the stomach or duodenum. In these cases, your doctor will consider of prescribing a protective medicine for the stomach.
- If you have asthma or other breathing disorder.
- If you have an infection - please see heading "Infections" below.
- If you have kidney disease or liver disease, are more than 60 years old or use ibuprofen long-term, your doctor may need to carry out checks on a regular basis. Your doctor will tell you the frequency of these checks.
- If you are dehydrated for example, due to diarrhoea, drink a lot of liquids and contact your doctor immediately as ibuprofen in this case could cause kidney failure as a result of dehydration.
- If you have Crohn's disease or ulcerative colitis because ibuprofen can worsen these conditions.
- If you observe any injuries, swelling or redness of the skin, trouble breathing (asphyxiation), immediately stop the treatment with the medicine and contact your doctor or nurse.
- If you have varicella as complications can occur.
- If you have hereditary disorder of the porphyrin metabolism (e.g. acute intermittent porphyria).
- If you drink alcohol around the same time of receiving this medicine, side effects related to stomach, intestines and nervous system may be increased.
- If you suffer from hay fever, nasal polyps or chronic obstructive respiratory disorders, you are at higher risk of allergic reactions. The allergic reactions may present as asthma attacks (so-called analgesic asthma), rapid swelling (Quincke´s oedema) or a rash.
- It is important that you are given the lowest dose that alleviates and control pain and are not given this medicine for longer than necessary to control your symptoms.
- Allergic reactions may occur with this medicine, mainly at the start of treatment. In this case, treatment should be discontinued.
- There have been few cases of aseptic meningitis with the use of this medicine. The risk is greater if you suffer from systemic lupus erythematosus and related connective tissue diseases.
- The use with concomitant NSAIDs including cyclooxygenase-2 selective inhibitors should be avoided.

Infections
Ibuprofen may hide signs of infections such as fever and pain. It is therefore possible that this medicine may delay appropriate treatment of infection, which may lead to an increased risk of complications. This has been observed in pneumonia caused by bacteria and bacterial skin infections related to chickenpox. If you take this medicine while you have an infection and your symptoms of the infection persist or worsen, consult a doctor without delay.

In general the habitual use of (several sort of) analgesics can lead to lasting severe kidney problems.

On prolonged use of painkillers, headache may occur that must not be treated with increased doses of the medicine.

During prolonged ibuprofen administration, regular checking of liver values, kidney function, and blood counts is required.

Ibuprofen can alter the following laboratory tests:
- Bleeding time (may be prolonged 1 day after the end of the treatment)
- Blood-glucose values (may be decreased)
- Creatinine clearance (may be decreased)
- Hematocrit or hemoglobin (may be decreased)
- Blood urea nitrogen, serum creatinine and serum potassium (may be increased)
- Liver function test: increased transminases levels

Tell your doctor if you are going to undergo clinical tests and you are using or you have recently used ibuprofen.

Children and adolescents
The safety and efficacy of Ibuprofen B. Braun in children and adolescents have not been established. This medicine should not be used in children and adolescents (below 18 years of age).

Other medicines and Ibuprofen B. Braun

Tell your doctor or nurse if you are taking, have recently taken or might take any other medicines.

Ibuprofen B. Braun may affect or be affected by some other medicines. For example:

- Other nonsteroidal anti-inflammatory drugs (NSAIDs) including COX-2 (e.g. celecoxib) may increase the risk of gastrointestinal ulcers and bleeding due to an additive effect.
- Medicines that are anti-coagulants (used for thinning blood and prevent clotting such as. acetylsalicylic acid, warfarin, ticlopidine).
- Cardiac glycosides such as digoxin (used to treat heart failure), phenytoin (used to treat epilepsy) or lithium (used to treat depression),may increase their blood levels when taking with ibuprofen.
- Methotrexate (used to treat certain types of cancers or rheumatism) taken at the same time as ibuprofen (within a range of 24 hours) can increase blood levels and risk of toxicity by methotrexate.
- Mifepristone (a medicine to terminate pregnancy).
- SSRIs-antidepressants, such as fluoxetine, may also increase the risk of bleeding of stomach and intestines.
- Medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol, angiotensin-II receptor antagonists such as losartan).
- Corticosteroids (such as hydrocortisone) (used for inflammation) because they increase the risk of ulcer or bleeding into stomach and intestines.
- Diuretics (medicines used for urination, such as bendroflumethiazide), as NSAIDs may reduce the effects of these medicines and it may increase the risk of kidney problems (using potassium sparing diuretics with ibuprofen can lead to high blood levels of potassium).
- Medicines containing probenecid and sulfinpyrazone may delay the excretion of ibuprofen.
- Cyclosporin and tacrolimus (used to avoid transplant rejection) may increase the risk of kidney damage.
- Sulfonylureas, such as glibenclamide (medicines used for diabetes). Control of blood glucose values is recommended when these medicines are used together.
- Antibiotics of the quinolone group, such as ciprofloxacin due to an increased risk for developing seizures (fits).
- Voriconazole, fluconazole (CYP2C9 inhibitors used for fungal infections) can increase blood levels of ibuprofen.
- Zidovudine, (used for HIV infection) due to increased risk of blood accumulation in joints and bruises.
- Aminoglycosides (a type of antibiotics) NSAIDs may decrease the excretion of aminoglycosides.
- Gingo biloba (a herbal medicine often used in dementia) may increase the risk of bleeding.

Some other medicines may also affect or be affected by the treatment with ibuprofen. You should therefore, always seek the advice of your doctor or nurse before you are given ibuprofen with other medicines.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or nurse for advice before you are given this medicine.

You must not be given this medicine during the third trimester (last 3 months) of pregnancy.

This medicine passes into breast milk but may be used during breast-feeding if it is used at the recommended dose and during the shortest possible time. However, if it is used at higher doses than 1200 mg daily or for longer periods, your doctor may recommend to interrupt the breast feeding.

Ibuprofen may make it more difficult to become pregnant. You should inform your doctor if you are planning to become pregnant or if you have problems to become pregnant.

Driving and using machines

This medicine, in single or short term use has no or negligible influence on the ability to drive and use machines. However, the occurrence of relevant side effects such as fatigue and vertigo can impair reactivity and the ability to drive a vehicle and/or use machines may be reduced. This particularly applies when combined with alcohol.

Ibuprofen B. Braun contains sodium. This medicinal product contains 360 mg sodium (component of cooking/table salt) per bottle. This is equivalent to 18.0 % of the recommended maximum daily dietary intake of sodium for an adult.

3. How Ibuprofen B. Braun is given

This medicine is prescribed to you only by a doctor and is only given to you by doctor or nurse in an environment with appropriate equipment.

The recommended dose for adults is 600 mg intravenously (a drip into a vein), another 600 mg dose can be administered after 6 to 8 hours depending on the intensity of the condition and response to treatment. The maximum daily dose of 1200 mg should not be exceeded.

The lowest effective dose should be used for the shortest duration necessary to relieve symptoms. If you have an infection, consult a doctor without delay if symptoms (such as fever and pain) persist or worsen (see section 2). Your doctor will also make sure that you have had enough fluids in order to minimize the risk of side effects to the kidney.

Use should be limited to situations where oral administration is inappropiate. Patients must switch to oral treatment as soon as this is possible.

This medicinal product is indicated for short-term acute treatment only and should not be used for more than 3 days.

Method of administration

For intravenous use. The solution should be administered by intravenous infusion over 30 minutes. This medicinal product is indicated for use as single dose. Inspect the solution before use. It should be discarded if any particulate matter or discoloration is observed.

If you are given more Ibuprofen B. Braun than you should
If you think you have been given more ibuprofen than you should immediately consult your doctor or nurse.

The symptoms can include nausea, stomach pain, vomiting (may be blood streaked), headache, ringing in the ears, confusion and shaky eye movement. At high doses, drowsiness, chest pain, palpitations, loss of consciousness, convulsions (mainly in children), inability to co-ordinate muscle movements, weakness and dizziness, blood in urine, cold body feeling, and breathing problems have been reported.

You might also suffer from low blood pressure, blueish colouration of the skin or mucous membranes (cyanosis), bleeding into stomach or intestines, as well as functional problems of the liver and kidneys.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The side effects can be minimized by using the lowest effective dose for the shortest time possible to treat the symptoms. You can get one or more of the known side effects of NSAIDs (see below). If you experience any of these side effects, you should stop using this medicine and consult a doctor as soon as possible. Elderly patients who use this drug are at greater risk for developing problems associated with side effects.

The most commonly observed adverse events are gastrointestinal side effects (affecting stomach and intestines). Peptic ulcers (stomach or intestinal ulcer), perforation (hole the wall of the stomach or intestine) or bleeding from the stomach or intestines, sometimes fatal, particularly in the elderly may occur. Nausea, vomiting, diarrhoea, flatulence, constipation, iIndigestion, abdominal pain, tarry stools, vomiting blood, ulcerative stomatitis (inflammation of the oral mucosa with ulceration), exacerbation of colitis (inflammation of large intestine) and Crohn's disease. Less frequently, gastritis (stomach inflammation) has been observed. Particularly the risk of bleeding into stomach and intestines occurring is dependent on the dose range and the duration of use. Edema (fluid accumulation in the tissues), high blood pressure and heart failure have been reported in association with NSAID treatment. Medicines like ibuprofen may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke.

Very rarely severe allergic reactions (including infusion site reactions, anaphylactic shock) and serious skin side effects such as bullous (blistering) reactions including Stevens-Johnson syndrome and toxic epidermal necrolysis (Lyell´s shyndrome), erythema multiforme, alopecia, (hair loss), skin becomes sensitive to light and allergic vasculitis (inflammation of a blood vessel) have been reported.

Exacerbation of inflammation related to infections (for example development necrotising fasciitis) coinciding with the use of NSAIDs has been described very rarely.

In exceptional cases, severe skin infections and soft-tissue complications may occur during a varicella infection.

Very common side effects (may affect more than 1 in 10 people):

- Tiredness or sleeplessness, headache and dizziness.
- Heartburn, abdominal pain, nauseas, vomiting, flatulence, diarrhoea, constipation and slight blood losses in stomach and intestines that may cause anaemia in exceptional cases.

Common side effects (may affect up to 1 in 10 people):

- Vertigo.
- Skin eruption.
- Pain and burning sensation in the administration site.
- Gastrointestinal ulcer, potentially with bleeding and perforation. Ulcerative stomatitis, exacerbation of colitis and Crohn´s disease.

Uncommon side effects (may affect up to 1 in 100 people):

- Insomnia (problems sleeping), agitation, irritability or tiredness, anxiety and restlessness.
- Visual disturbances.
- Tinnitus (ringing or buzzing in the ears).
- Inflammation of the stomach lining.
- Reduced production of urine and formation of oedemas, particularly in patients with high blood pressure or kidney problems, nephrotic syndrome, interstitial nephritis that may be accompanied by acute renal insufficiency.
- Urticaria, pruritus, purpura (including allergic purpura), skin rash.
- Allergic reactions with skin rashes and itching, as well as asthma attacks (possibly with drop of blood pressure).

Rare side effects (may affect up to 1 in 1,000 people):

- Reversible toxic amblyopia (double vision).
- Difficulty hearing.

- Narrowing ot the oesophagus (blood vessels in gullet), complications of diverticula of the large bowel, unspecific haemorrhagic colitis. If there is bleeding into stomach or intestines, it can cause anemia.
- Damage of kidney tissue (papillary necrosis), particularly in long-term therapy, increased serum uric acid concentration in the blood.
- Yellowing of the skin or whites of the eyes, liver dysfunction, liver damage, particularly in long-term therapy acute hepatitis (inflammation of the livers).
- Psychotic reactions, nervousness, irritability, confusion or disorientation and depression.
- Stiff neck.

Very rare side effects (may affect up to 1 in 10,000 people):

- Disorders of blood cell formation (anaemia, leukopenia, thrombocytopenia, pancytopenia, agranulocytosis). The first symptoms are: fever, sore throat, surface mouth ulcers, flu-like symtoms, severe fatigue, nasal and skin bleeding.
- Palpitations (rapid heartbeat), heart failure, myocardial infarction.
- Arterial hypertension
- Aseptic meningitis (stiff neck, headache, nausea, vomiting, fever or confusion). Patients with autoimmune disorders (SLE, mixed connective-tissue disease) appear to be predisposed.
- Inflammation of oesophagus (gullet) or pancreas, narrowing of the bowel.
- Asthma, difficulty breathing (broncospasm), shortness of breath and wheezing.
- Systemic lupus erythematosus (an autoimmune disease), severe allergic reaction (face oedema, swelling of the tongue, swelling of the throat with constriction of the airways, difficulty breathing, rapid heartbeat and decreased blood pressure and life threatening shock).

Not known side effects (frequency cannot be estimated from the available data):

- Liver insufficiency.
- Site of injection reactions such as swelling, bruising or bleeding.
- A severe skin reaction known as DRESS syndrome can occur. Symptoms of DRESS include: skin rash, fever, swelling of lymph nodes and an increase of eosinophils (a type of white blood cells).
- A red, scaly widespread rash with bumps under the skin and blisters mainly localized on the skin folds, trunk, and upper extremities accompanied by fever at the initiation of treatment (acute generalised exanthematous pustulosis). Stop using Ibuprofen B. Braun if you develop these symptoms and seek medical attention immediately. See also section 2.

Reporting of side effects
If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Ibuprofen B. Braun

Keep this medicine out of the sight and reach of children.

This medicinal product does not require any special storage conditions.

The product should be used immediately after opening.

For single use only. Any unused solution should be discarded.

Do not use this medicine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

Do not use this medicine if you notice any particles or discoloration.

6. Contents of the pack and other information

What Ibuprofen B. Braun contains
- The active substance is ibuprofen. Each 100 ml bottle contains 600 mg of ibuprofen.
- The other ingredients are L-arginine, sodium chloride, hydrochloric acid, sodium hydroxide, water for injection.

What Ibuprofen B. Braun looks like and contents of the pack

Clear and colorless to pale yellow solution for infusion, without any particulate matter.

The solution is contained in closed LDPE bottles of 100ml with an external cap in packs of 10 bottles and 20 bottles.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
B. Braun Melsungen AG
Carl-Braun-Straße 1
34212 Melsungen
Germany

Manufacturer
B. Braun Medical, S.A.
Ctra. Terrasa, 121
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08191 Barcelona – Spain

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder.

This medicinal product is authorised in the Member States of the EEA under the following names:

AT	Ibuprofen B. Braun 600 mg Infusionslösung
BE	Ibuprofen B. Braun 600 mg oplossing voor infusie.
BG	Ибупрофен Б. Браун 600 mg/100 ml инфузионен разтвор
CZ	Ibuprofen B. Braun
DE	Ibuprofen B. Braun 600 mg Infusionslösung
DK	Ibuprofen B. Braun 600 mg infusionsvæske, opløsning
EE	Ibuprofen B. Braun, 600 mg infusioonilahus
ES	Ibuprofeno B. Braun 600 mg solución para perfusión
FI	Ibuprofen B. Braun 600 mg infuusioneste, liuos
FR	Ibuprofène B. Braun 600 mg, solution pour perfusion
HU	Ibuprofen B. Braun 600 mg oldatos infúzió
IE	Ibuprofen B. Braun 600 mg solution for infusion
IT	Ibuprofene B. Braun Melsungen 600 mg Soluzione per infusione
LU	Ibuprofen B. Braun 600 mg solution pour perfusion
LV	Ibuprofen B. Braun 600 mg šķīdums infūzijām
LT	Ibuprofen B. Braun 600 mg infuzinis tirpalas
NL	Ibuprofen B. Braun 600 mg oplossing voor infusie
NO	Ibuprofen B. Braun 600 mg infusjonsvæske, oppløsning
PL	Ibuprofen B. Braun
PT	Ibuprofeno B. Braun 600 mg solução para perfusão
RO	Ibuprofen B. Braun 600 mg soluţie perfuzabilă
SE	Ibuprofen B. Braun 600 mg infusionsvätska, lösning
SI	Ibuprofen B. Braun 600 mg raztopina za infundiranje
SK	Ibuprofen B. Braun
UK	Ibuprofen 600 mg Solution for Infusion

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